510(k) Summary

Submitter: Captiva Spine, Inc.

DEC - 1 2009

Contact Person:
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Date Prepared: July 2, 2009

Trade Name: Pivotec Lumbar Interbody Fusion Device (LIFD)

Classification Name and Number:
Class II
Intervertebral Body Fusion Device
21 CFR 888.3080

Product Code: MAX

Predicate Device(s): The subject device is substantially equivalent to the following devices:

Lumbar I/F Cage (P960025)
Marketed and distributed by DePuy

Ray Threaded Fusion Cage (TFC)™ (P950019)
Marketed and distributed by Stryker (originally approved by Surgical Dynamics)

AVS TL PEEK Spacer (K083661)
Marketed and distributed by Stryker

Device Description: The Pivotec LIFD is an intervertebral body fusion device for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments and promote fusion. The device is made of PEEK-Optima with Tantalum markers and is provided in various configurations and heights, containing a hollow core to receive bone autograft. Placement is achieved with an insertion instrument that allows for manipulation of the implant within the intra-vertebral disc space.

Intended Use:	The Pivotec LIFD implant is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Pivotec LIFD Implant is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.
Functional and Safety Testing:	Mechanical testing of the subject device consisted of static and dynamic compression, static and dynamic compression shear and subsidence. All testing was conducted in accordance with ASTM F2077-03 and ASTM F2267-04. The device performed as designed and met, or exceeded, all product specifications.
Conclusion:	The documentation provided demonstrates that the Pivotec LIFD is substantially equivalent to the predicate devices listed above. This conclusion is based on the devices' similarities in materials, design, indications for use, function and mechanical function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Captiva Spine, Inc.
% Sanacor, LLC
Mr. Mike Ensign
Director of Engineering
P.O. Box 1196
Pleasant Grove, Utah 84062

DEC - 1 2009

Re: K092017
Trade/Device Name: Pivotec Lumbar Interbody Fusion Device (LIFD)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: II
Product Code: MAX
Dated: July 2, 2009
Received: July 6, 2009

Dear Mr. Ensign:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___NA____

Device Name: Pivotec Lumbar Interbody Fusion Device (LIFD)

Indications for Use:

The Pivotec LIFD implant is an intervertebral body fusion deviceindicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Pivotec LIFD Implant is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092017